IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/532,320 Confirmation No. 9143
Applicants	:	Herman Jan Tijmen Coelingh Bennink et al.
Filed	:	June 2, 2006
Title	:	PHARMACEUTICAL COMPOSITIONS COMPRISING ESTETROL DERIVATIVES FOR USE IN CANCER THERAPY
Group Art Unit	:	1616
Examiner	:	Kristie Latrice BROOKS
Customer No.	:	28289

DECLARATION

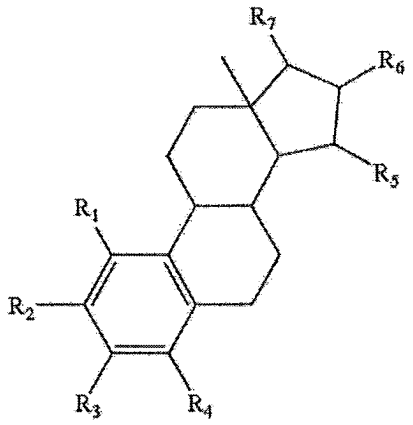
I, Westhoff, Carolyn L. declare and state the following:

1. A detailed listing of my publications, together with details of my education, are given in my *curriculum vitae* which is attached as Exhibit A.

2. Based on my academic training and professional experience, I consider myself an expert in the field of estrogen-related therapies and treatments, and I was such a person in 2002.

3. I have received a copy of the above referenced US patent application.

4. I understand that this patent application relates to a new method of treating or preventing estrogen-suppressed tumors that comprises administration of the following estrogenic component:



wherein R_1, R_2, R_3 and R_4 independently are a hydrogen atom, a hydroxyl group or an alkoxy group with 1-5 carbon atoms. R_5, R_6 and R_7 are hydroxyl groups. No more than three of R_1, R_2, R_3 and R_4 are hydrogen atoms. The invention also includes using variations of this formula, such as precursors capable of liberating a substance according to the aforementioned formula and mixtures of one or more of the aforementioned substances and/or precursors. One embodiment of the aforementioned formula is estetrol.

5. I have received copies of the following references that I have been told have been cited in Office Actions that were issued in relation to co-pending US patent applications that also relate to the use of the aforementioned estrogenic component in therapeutic treatment, methods of contraception and hormone replacement therapy.

D1 US 5,340,584 (Spicer et al.)

D2 US 5,211,952 (Spicer et al.)

D3 US 5,340,586 (Pike et al.)

D4 US 2004/0192598 (Kragie)

D5 Holinka, Biology of Reproduction, 1979; 20(2): 242-246 [1]

D6 Holinka, Biology of Reproduction, 1980; 20(4): 913-926 [2]

6. I have been asked to comment on my understanding of the state of the art prior to October 23, 2002, which I understand is the priority date for the aforementioned US patent application. No. 10/532,320. Particularly, I have been asked whether, prior to October 23, 2002, a person of ordinary skill in the art would have considered it obvious to use estetrol in

therapeutic treatment. More particularly, I have been asked whether, prior to the October 23, 2002, a person of ordinary skill in the art would have been motivated to use estetrol in the treatment of prevention of estrogen-suppressed tumors, and whether the discovery that estetrol was pharmacologically useful in these applications is unexpected and surprising

7. It is my view that, prior to October 23, 2002, for the reasons presented below, a person of ordinary skill in the art would not have expected estetrol to be pharmacologically useable, and that the Applicants were the first to discover the pharmacological usefulness of estetrol. In addition, and more particularly, it is my opinion that, prior to October 23, 2002, a person of ordinary skill in the art:

- would not have expected that estetrol can be used to treat estrogen-suppressed tumors, such as colorectal tumors or prostate tumors.
- would not have expected estetrol to be pharmacologically active when orally administered.

8. I declare that before October 23, 2002 I had no knowledge of any concrete pharmacological application of estetrol. Furthermore, before October 23, 2002, I did not expect that estetrol can be used effectively as a drug in therapeutic treatments or in hormonal contraceptives. Based on the data from scientific literature that was available before October 23, 2002, I would have expected estrogenic activity of estetrol to be too low for pharmacological applications, such as the ones recited in Applicants' claims.

9. My view that a person of ordinary skill in the art would not have expected estetrol to be pharmacologically active is supported by leading textbooks in the field of endocrinology. In "Clinical Gynecologic Endocrinology and Infertility" [3] estetrol is solely mentioned in Chapter 8 (The Endocrinology of Pregnancy) under the subheading "Measurement of Estrogen in Pregnancy" (page 287) and in the index. On page 287 it is stated that "Estetrol (15alpha-hydroxyestriol) is formed from a fetal precursor and is very dependent on 15alpha-hydroxylation activity in the fetal liver. The capacity for 15alpha-hydroxylation of estrogens increases during fetal life, reaching maximum at term. This activity then declines during infancy and is low, absent or undetectable in adults. There is no clinical use for maternal blood or urine estetrol

measurements during pregnancy. The clinical use of maternal blood and urine estetrol measurements is of no advantage over the usual estriol assessment."

10. The unexpected pharmacological activity of estetrol is associated with Applicants' discovery that estetrol has a surprisingly long *in vivo* elimination half-life. Applicants' finding that estetrol has a terminal elimination half-life of about 28 hours, which is very much longer than that of the other pregnancy hormone estriol (5-10 minutes), was very unexpected and provided the clue towards its pharmacological usefulness as will be further explained below.

11. I appreciate that the cited references D1 to D4 contain references to estetrol within a lengthy list of other estrogens. Furthermore, I have read the Holinka articles" D5 and D6, which report that parenterally administered estetrol produced estrogenic changes in the immature rat uterus.

12. I declare that although the cited references D1 to D4 list estetrol among candidate estrogens for pharmaceutical use, it is my view that a person of ordinary skill in the art having knowledge of the aforementioned patent publications D1 to D4 and the "Holinka articles" D5 and D6, would not have expected estetrol to be pharmacologically useable for the reasons presented below.

13. The mere mentioning of estetrol in a long list of candidate estrogens in D1 to D4 without any experimental data to support the viability of pharmaceutical uses described in these patents, in my view would not have provided a person of ordinary skill in the art with any motivation to actually employ estetrol in these pharmaceutical uses.

14. In Holinka (1979)[1] the estrogenic activity of estetrol was evaluated by examination of uterine responses to subcutaneous administration of estetrol in doses of 10 and 50 µg/100g body mass. The effects were compared to those obtained by administration of 1 µg/100g body mass estradiol or estriol. The last paragraph of the abstract of Holinka (1979) reads as follows "It is concluded that estetrol administered as a single dose or in 2 doses at a 24 h interval is a weak estrogen which produces effects of short duration. It cannot, however, be considered

entirely devoid of estrogenic activity, even though true uterine hyperplasia, as estimated by DNA content, was not promoted by administration of the two 50 μg/100 g bw doses of estetrol".

15. Holinka (1980)[2] describes the results of a study that aimed to extend the study described in Holinka (1979). In this follow-up study estrogenic effects on immature rat uterus of estetrol and the antiestrogen tamoxifen were compared with those of estradiol and estriol. This time, estetrol was injected subcutaneously for 3 days at a dose of 50 μg/100g body mass, a dose 50 times greater than the dosages of estradiol and estriol that were administered subcutaneously (at a dose of 1 μg/100g body mass). The last paragraph of the abstract of Holinka (1980) reads as follows: "In general estradiol treatment promoted the most marked changes, followed by tamoxifen, estriol and estetrol. On the basis of the present biochemical and morphological results, it is concluded that estetrol and tamoxifen have estrogenic effects on the immature rat uterus. However, the estrogenic potency of estetrol, relative to estradiol or estriol was low at the dosage and timing of administration used in these experiments; effects of estetrol introduced in the circulation at a constant rate were not evaluated. These results suggest that the conversion of estradiol to estetrol in the human fetus represent an efficient mechanism of inactivation of the placental hormone." Specifically, even though Holinka et al administered 50 times more estetrol than estradiol or estriol, the observed uterotropic effects of estetrol were still smaller than those of estradiol or estriol. Thus, from Holinka (1980), one of ordinary skill in the art would expect estetrol to be more than 50 times less effective than a weak estrogen, such as estriol.

16. It is my view that a person of ordinary skill in the art would have deduced from the Holinka articles that estetrol has estrogenic activity, but that it is a much weaker estrogen than the already weak estrogen estriol, given that estetrol injected subcutaneous at 50 μg/100g body mass exhibited less estrogenic activity than estriol injected subcutaneous at 1 μg/100g body mass. Estriol is a very weak estrogen due to its low receptor affinity in combination with its very short half-life of 5-10 minutes. Since the Holinka articles teach that estrogenic activity of estetrol is at least 50 times lower than that of a weak estrogen for which very few practical applications exits, the Holinka articles would not have provided a motivation for a person of ordinary skill in the art to investigate the potential pharmacological usefulness of estetrol.

17. Applicants have demonstrated that, contrary to what a person of ordinary skill in the art would have expected, estetrol is pharmacologically very active. The unexpected pharmacological activity of estetrol is associated with its surprisingly long *in vivo* elimination half-life. Whereas, under comparable conditions, the human estrogens estradiol and estriol have terminal elimination half-lifes of about 30 minutes and 5-10 minutes respectively, estetrol has a terminal elimination half-life of about 28 hours. A person of ordinary skill in the art would have expected estetrol to be more comparable to estriol than estradiol given that (i) estetrol differs from estriol by only 1 hydroxy group and from estradiol by 2 hydroxy groups and (ii) both estriol and estetrol are produced during pregnancy. Hence, Applicants' finding that estetrol has a terminal elimination half-life that is 168-336 higher than that of the other pregnancy hormone estriol, was very unexpected and provided the clue towards its pharmacological usefulness. Based on my knowledge of the relevant art, I conclude that Applicants are the first to have discovered estetrol's pharmacological usefulness. As explained herein before, it is my view that, prior to October 23, 2002, a person of ordinary skill in the art would not have anticipated this usefulness.

18. In addition, I conclude that Applicants are the first to have discovered the use of estetrol in the treatment of estrogen-suppressed tumors, such as colorectal tumors and prostate tumors. The application of estetrol in the treatment of estrogen-suppressive tumors offers unanticipated advantages that are linked to the surprising finding that estetrol has selective estrogen antagonistic activity, more particularly to the discovery that estetrol acts as an estrogen antagonist in breast tumor. It is generally accepted that estrogens increase the risk of "estrogen-stimulated cancers", e.g. breast cancer in females by inducing an estrogen receptor mediated increase in the frequency of cell division (proliferation) within these tissues. Cell division is essential in the complex process of genesis of human cancer since it *per se* increases the risk of genetic error, particularly genetic errors such as inactivation of tumor suppressor genes. Since the incidence of the estrogen-stimulated cancers in industrialized countries is very high, treatment of estrogen-suppressed tumors with estrogens is associated with a significant risk factor for the development of e.g. breast cancer. In the case of estetrol, however, this risk is mitigated due to its selective estrogen antagonistic activity, notably its estrogen antagonistic activity in breast tumors. In my opinion, prior to October 23, 2002, a person of ordinary skill in the art could not have foreseen the selective estrogen antagonistic activity of estetrol and

consequently, before that date a skilled person would not have envisaged the benefits associated with the use of estetrol in the treatment of estrogen-suppressed tumors.

19. Finally, I conclude that Applicants are the first to have discovered estetrol's high oral bioavailability. This finding is truly surprising as other human estrogens, notably estradiol, estriol and estrone, exhibit low oral bioavailability because they are largely metabolized into inactive metabolites during the so called "first pass" through the liver after oral administration. It is my opinion that, given that estetrol's estrogen receptor affinity was known to be considerably lower than that of estradiol and estriol, a person of ordinary skill in the art, being aware that known human estrogens are largely metabolized during the first pass, could not have anticipated the high oral bioavailability of estetrol. Thus, in my view, prior to October 23, 2002, a person of ordinary skill in the art could not have anticipated estetrol's oral pharmacological activity.

20. As mentioned herein before, it is my view that a person of ordinary skill in the art could not have anticipated the advantageous pharmacological properties of estetrol that Applicants have described in the above referenced pending patent application and that have been reported in scientific articles that were published after October 23, 2002. In particular, such a skilled person could not have foreseen the favorable pharmacokinetic (ADME) and pharmacodynamic properties of estetrol. These favorable properties of estetrol are remarkable since they are much less manifest in other human estrogens, notably estradiol, estriol and estrone. The unexpected favorable properties of estetrol that have been described by Applicants in the aforementioned pending patent applications and that were not known before October 23, 2003 include:

A. Long *in vivo* elimination half-life in the human

- In the first human study with estetrol, a dose-independent terminal elimination half-life of about 28 hours after single oral administration to early postmenopausal women was demonstrated [4,5]. Terminal elimination half-lifes of the human estrogens estradiol and estriol under comparable conditions are about 30 minutes and 5-10 minutes respectively [3].

B. No binding affinity for sex hormone binding globulin (SHBG)

- Competitive ligand binding assays did not detect any binding of estetrol to the SHBG steroid-binding sites [4,6]. By contrast, estradiol is bound by SHBG with high affinity [6].

C. No ERα-mediated increase in SHBG production by HepG2 or Hep89 cells

- Fluorometric assays in wild-type human HepG2 and Hep89 cells showed that estetrol does not stimulate ERα-mediated increases in SHBG production by these cells, in contrast to estradiol and estriol [4,6].

D. No conversion to other active metabolites

- Estetrol is an end-stage product of estrogen metabolism [4,5,7]. In contrast, especially after oral administration, estradiol is rapidly and reversibly converted by the liver to the estrogenic metabolites estrone and estrone sulfate.

E. No significant inhibition of P450 enzymes

- At a concentration of 10 µmol/l estetrol has no inhibitory effect on any recombinant human P450 enzymes CYP1A2, CYP2C9, CYP2C19, CYP2D6 and CYP3A4. In contrast, at the same concentration estradiol moderately inhibits CYP1A2 and strongly inhibited CYP2C19 [4,7].

F. Highly selective binding to estrogen receptors ERα and ERβ

- Estetrol tested at a prime concentration of 10 µmol/l, did not show significant (>20%) inhibition of the binding of the respective ligands in 123 of the 124 assays studied (Estetrol only inhibited binding of prazosin at the adrenergic α_{1B} receptor by 23%) [4,7].

G. Estrogen agonist in bone, vagina, myometrium, endometrium and brain, but estrogen antagonist in breast tumor tissue in the presence of estradiol

- Estetrol significantly and dose-dependently inhibited the OVX-related increase in osteocalcin levels, increased bone mineral density and content, and increased bone strength [4,8].
- Estetrol is effective in preventing temperature rises dose-dependently in an animal model considered representative for menopausal vasomotor symptoms [4,9].
- In the modified Allen-Doisy test estetrol was found to have dose-dependent estrogenic effects on the vagina and on the uterus of ovariectomized rats including the endometrium [4,10].

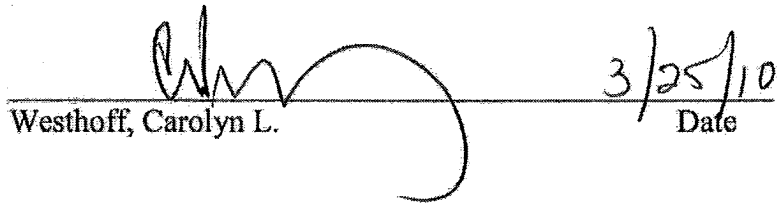
- Estetrol at a twice-daily dose of 0.3 mg/kg and above effectively inhibited ovulation in regularly cycling female rats [4,11].
- Estetrol dose-dependently prevents the growth of chemically induced (DMBA) mammary tumors in rats and has the potential to reduce the number and size of pre-existing mammary tumors [4,12]. By contrast it is well-established that estradiol has proliferative effects on breast tumor cells and tissue.

H. Oral absorption in the human with a strong dose-response relationship suggesting high oral bioavailability
   - In a first-in-human study four single doses of 0.1, 1, 10 and 100 mg estetrol were administered orally to early postmenopausal women. High oral bioavailability, a strong dose-response relationship and a long elimination half-life (see A) were found. For the first time (oral) pharmacodynamic effects of estetrol were observed since the data showed a strong suppression of follicle stimulating hormone (FSH) with the 100 mg dose and a dose-dependent inhibition of luteinizing hormone (LH) levels [4,5].

The above mentioned features A to D imply that the estrogenic activity of estetrol is much more pronounced than could have been anticipated on the basis of the estrogen receptor affinity studies described in scientific literature before October 23, 2002. Features E and F indicate that it is unlikely that estetrol administration will induce undesirable side-effects. Feature G indicates that estetrol may suitably be used in the treatment of estrogen-suppressed tumors without enhancing the risk of breast cancer. Feature H indicates that estetrol has potential as a once-a-day oral drug for human use.

21. I have not been compensated for the execution of this declaration, or any time I spent relating to this declaration.

22. I declare further that all statements made herein are true to my knowledge; and that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



Westhoff, Carolyn L.

3/25/10
Date

References

[1] Holinka et al., *In vivo effects of estetrol on the immature rat uterus.* Biol Reprod 20 (1979) 242-6.

[2] Holinka et al., *Comparison of effects of estetrol and tamoxifen with those of estriol and estradiol on the immature rat uterus.* Biol Reprod 22 (1980) 913-26.

[3] Leon Speroff, Robert H. Glass and Nathan G. Kase. *Clinical Gynecologic Endocrinology and Infertility.* Baltimore, Maryland, USA. Lippincott Williams & Wilkins, 1999.

[4] Coelingh Bennink et al., *Estetrol Review: profile and potential clinical applications*, Climacteric 2008; 11 (Suppl 1): 47-58

[5] Visser et al., *First human exposure to exogenous single-dose oral estetrol in early postmenopausal women*, Climacteric 2008; 11 (Suppl 1): 31-40

[6] Hammond et al., *Estetrol does not bind sex hormone binding globulin or increase its production by human HepG2 cells*, Climacteric 2008; 11 (Suppl 1): 41-46

[7] Visser et al., *In vitro effects of estetrol on receptor binding, drug targets and human liver cell metabolism*, Climacteric 2008; 11 (Suppl 1): 64-68

[8] Coelingh Bennink et al., *Oral bioavailability and bone-sparing effects of estetrol in an osteoporosis model*, Climacteric 2008; 11 (Suppl 1): 2-14

[9] Holinka et al., *Preventive effect of oral estetrol in a menopausal hot flush model*, Climacteric 2008; 11 (Suppl 1): 15-21

[10] Heegaard et al., *Estrogenic uterovaginal effects of oral estetrol in the modified Allen-Doisy test*, Climacteric 2008; 11 (Suppl 1): 22-28

[11] Coelingh Bennink et al., *Ovulation inhibition by estetrol in an in vivo model*, Contraception 2008; 77: 186-190

[12] Coelingh Bennink et al., *Estetrol, a pregnancy specific human steroid, prevents and suppresses mammary tumor growth in a rat model*, Climacteric 2008; 11 (Suppl 1): 29

BIOGRAPHICAL SKETCH FOR

DR. CAROLYN L.WESTHOFF

1) **Revised** January, 2008

2) **CAROLYN L. WESTHOFF**
DOB - 11/17/1951
Birthplace - Michigan
Citizenship - U.S.
SSN - 381-56-6836

3) **Academic Training**
University of Michigan, B.S. with distinction, Zoology, 1972.

University of Michigan, M.D., 1977.

London School of Hygiene and Tropical Medicine, M.Sc. with distinction, Epidemiology, 1983.

4) **Traineeships**
Intern, 1977-78, Department of Internal Medicine, Henry Ford Hospital, Detroit, Michigan.

Resident, 1978-81, Chief Resident, 1981-82, Department of Obstetrics and Gynecology, S.U.N.Y. - Downstate Medical Center, Brooklyn, New York.

Research Fellow, 1983-84, Department of Community Medicine and General Practice, University of Oxford, Oxford, U.K.

Fellow, Hedwig van Ameringen Executive Leadership in Academic Medicine(ELAM). 2001-2002

5) **Board certification**
National Board of Medical Examiners, 1978
American Board of Obstetrics and Gynecology, 1986
-recertified, 1996
-annual board certification, 2005, 2006, 2007

6) **Military service** - none

7) **Professional organizations**

American College of Obstetrics and Gynecology
American Medical Women's Association (Board of Directors, 2004-05)
American Public Health Association
Association of Reproductive Health Professionals (Board of Directors)
New York Obstetrical Society (Executive Committee, Vice-President 2004-05, President, 2005-2006)
Society of Family Planning (Board member, Secretary 2005-07)
American Gynecologic and Obstetric Society(AGOS) elected 2007
Elected to the Institute of Medicine, 2007

8) **Academic appointments**

Assistant Professor, 1984-86, Department of Obstetrics and Gynecology, State University of New York (S.U.N.Y.), Health Sciences Center at Brooklyn (formerly, Downstate Medical Center), Brooklyn, New York

Assistant Professor of Obstetrics and Gynecology and Public Health (Epidemiology) 1986 - 1993, Columbia University

Associate Professor of Clinical Obstetrics and Gynecology and Public Health (Epidemiology) 1993 - 2000, Columbia University

Professor of Obstetrics and Gynecology, College of Physicians and Surgeons; Director, Division of Prevention and Ambulatory Care and Director of Family Planning Fellowship, Columbia University 2000 – **present**

Professor of Epidemiology and Population and Family Health, Mailman School of Public Health, Columbia University, 2000 - **present**

9) **Hospital appointments**

Attending Physician, 1984-86, State University Hospital and Kings County Hospital Center, Brooklyn, New York.
Assistant Attending Physician, 1986 - 1993,
Medical Director, Family Planning Clinics, 1988-**present**,
Associate Attending Physician, 1993 - 1999
Attending Physician, 2000 - **present**
Medical Director, Special GYN Services, 2001 - **present**
Columbia University Medical Center, New York

10) **Honors**

Milbank Memorial Fund Scholar, 1982-87
Calderone Prize, Columbia University School of Public Health, 1991
Elaine B. Lesser Prize, Comprehensive Cancer Center, 1991
New York Obstetrical Society, elected to membership, 1992
ACOG Women's Health Leadership Program, 2001
Women Making History, Planned Parenthood of NYC, 2002
Abram Sager Lectureship, University of Michigan, 2002
Shirley Sacks Award, National Coalition for Women's Health, 2003
Reproductive Rights Project Award, New York Civil Liberties Union, 2004
C. Lalor Burdick Award, National Abortion Federation, 2005
Elected to AGOS, 2006
NAMS/Warner Chilcott Innovations in Perimenopausal Contraception Research Award, 2007
Elected to the Institute of Medicine, National Academy of Sciences, 2007

11) **Fellowship and grant support**

Milbank Memorial Fund Scholar, 1982-87

NICHD Contract # N01-HD-52908. Luteal Phase Progesterone Level Changes Following Tubal Sterilization. 1985-91. Co-Investigator.

NCI-RO3-CA47827. CA-125 levels in the blood of normal women. Principal Investigator. Awarded 6/88. Small grants program for epidemiology.

Columbia University Comprehensive Cancer Center, Institutional Research Grant. Use of transvaginal sonography for screening menopausal ovaries. Principal Investigator. Awarded 8/88.

NCI-RO1-CA50658. Case Control Study of Benign Ovarian Neoplasms. Principal Investigator. 1991-94.

DHHS - 02-H-000468:13, Reproductive and sexual health care services for women. Program director, L. Tiezzi. Role in project, Medical Director, 7/1/93 - 6/30/94; 7/1/74 - 6/30/95; 7/1/95 - 6/30/96, to **present**. (renewal submitted annually)

American Cancer Society - #IRG-177A. Occurrence and epidemiology of germinal inclusion cysts of the ovary. Principal Investigator, effort as needed. 1991-92. Continuation of work funded by Lesser Prize and Calderone Award.

NCI - CA095299. Training Program in Cancer Epidemiology, Biostatistics and Environmental Sciences. Co-investigator, effort as needed. 7/1/90 - 6/30/95.

NCI - RO3-CA57404-01. Infertility and Ovarian Cancer: A Pilot Study. Principal Investigator. 5/15/92 - 4/15/93 (no cost extension to 4/94).

NICHD Decision making concerning Norplant use and discontinuation. Med. advisor, as needed. 9/1/92 - 8/31/97. (P.I. - A. Davidson)

NCI - RO3 CA63016-01 . Germinal inclusion cysts of the ovary: the epidemiology. Co-principal investigator. 10/1/93 - 9/30/94.

NCI - RO3 CA64194-01. Family history of cancer in women with ovarian tumors. P.I. 7/1/94 - 6/30/96.

The Population Council. Evaluation of the efficacy, safety and acceptability of mifepristone and misoprostol in inducing abortion in pregnant women with amenorrhea of up to 63 days. Clinical Center Principal Investigator. 12/5/94 - 6/4/95.

SRA Technologies, Inc (under contract to NCI). Ovarian and breast cancer in an infertile cohort (co-author of NCI protocol). Clinical Site Principal Investigator. 1/1/95 - 12/31/99.

Wyeth-Ayerst Laboratories. Norplant System observational cohort study. Principal Investigator. 7/01/95 - 6/30/02.

Rudin (Louis and Rachel) Foundation. Training of medical students in family planning service delivery. Program Director 1996-**present**. Renewed annually.

NICHD. Data Coordinating Center for the Reproductive Medicine Network. 4/1/96- 3/31/00. Original P.I. R. Canfield, C.W. Co-P.I.

Anonymous Foundation. Fellowship program in family planning and contraception. Program Director, starting 1997-**present**. Renewed annually.

Pharmacia & Upjohn. Multi-center open-label clinical tiral of the contraceptive effectiveness and safety of Cyclo-Provera. Clinical center, Principal Investigator. 5/97 - 12/98.

Fan Fox and Leslie Samuels Foundation, Inc. Adolescent girls with chronic illnesses: sexuality and contraception counseling project. Co-principal investigator (with K. Soren of Pediatrics). 7/15/97-9/30/98.

New York Community Trust. Adolescent girls with chronic illnesses: sexuality and contraception counseling project. Co-principal investigator (with K. Soren of Pediatrics). 9/1/98-8/31/99.

Gynétics. A prospective, open label study of levonorgestrel 0.75mg tablets as an emergency contraceptive agent. P.I. Start date 4/1/99.

William and Flora Hewlett Foundation. 2000-4555 Contraceptive Research and Training. 1999-2003 P.I.

NICHD –R03-HD39239 - A Novel Oral Contraceptive Initiation Method. 7/1/00 – 6/30/01. P.I., P. Murphy, C.W. Co-P.I.

NICHD-R03-HD39776 - Oral Contraceptives for Dysmenorrhea in Adolescent Girls. 12/1/00 -11/30/02. P.I., A. Davis, C.W. Co-P.I.

Berlex. A Multicenter, Open-Label, Uncontrolled Trial with Levenorgestrel-Releasing Intrauterine System (LNG IUS) to Evaluate the Insertion and Counseling Procedures. 10/2/00 - 8/31/02. P.I.

NICHD N01-HD13321 – RCT on Management of Early Pregnancy Failure: Clinical Centers. 4/1/01 – 4/1/04. P.I.

NICHD. N01-HD-13314 - A Randomized Controlled Study of the Efficacy, Safety, and Acceptability of BufferGel. 4/1/01 - 7/31/04. P.I.

NICHD-R21-AT00836 - Effects of Hypericum Perforatum on Oral Contraceptives. 9/1/01 - 8/31/03. P.I., P. Murphy, C.W. Co-P.I.

Pharmacia. (Investigator Initiated) Observational study of novel methods for the initiation of the Depo-Provera contraceptive injection, 6/1/02 – 12/1/02. P.I.

NIH (NIA) R01 AG15922-01. Alzheimer's Disease prevention trial with estrogen, Co-Investigator. P.I. M. Sano, 7/1/98-6/30/03.

Pharmacia & Upjohn. Contraception study of medroxyprogesterone acetate and estradiol cypionate injectable suspension administered subcutaneoulsy. 1/4/02 – 1/3/03. P.I.

University of Pittsburgh (Subcontract) Mifepristone and Misoprostol for abortion 63 days gestation: RCT comparison of Misoprostol 6 to 8 hours versus 24 hours following Mifepristone. 5/1/02 – 8/31/03. P.I.

NICHD-R01-HD42413 - RCT of a Novel Oral Contraceptive Initiation Method. 8/29/02-8/31/05 P.I.

Ortho McNeil Pharmaceutical. A Randomized, open-label, multicenter study comparing the bleeding profile Ortho Evra (Norelgestremin/Ethinyl Estradiol) continous regimen versus Ortho Evra cyclic regimen. 6/7/02-5/30/03. P.I.

Besins International. A Phase II multicenter randomized controlled trial of 4-hydroxy tamoxifen gel for cyclical mastalgia. 12/10/02 – 10/1/03. P.I.

ASPH/CDC/ATSDR. Quick Start: Improving Adolescents Contraceptive Compliance. 10/1/02 – 9/30/04, P.I., V. Rickert, Co-.I., C. Westhoff.

Organon Pharmaceuticals. (Investigator Initiated) A randomized trial comparing the immediate initiation of the monthly vaginal ring for birth control and the immediate initiation of a triphasic oral contraceptive. 1/01/03 – 12/31/03, P.I.

NICHD R01 AG15922-01. Alzheimer's Disease Prevention Trial with Estrogens. 7/1/03 – 8/31/08. P.I. M. Sano, Co-P.I., C. Westhoff.

William and Flora Hewlett Foundation (2003-8871) . Contraceptive Research and Training. 7/03 – 6/07 P.I.

NICHD HD43374002 – Contraceptive Clinical Trials Network – Female Contraceptive Clinical Trial: A randomized controlled study of the efficacy, safety, and acceptability of C31G. 4/1/04– 2/28/11. P.I.

NICHD HD43374002– Contraceptive Clinical Trials Network – Female Clinical Trial topic area- Core 4/1/05 – 3/31/11. P.I.

Wyeth Pharmaceuticals – A Phase 3, multicenter, open-label study to evaluate the safety and efficacy of Levonorgestrel 90 ug and Ethinyl Estradiol 20 ug in a continuous daily regimen for oral contraception. 5/1/03 – 4/30/05. P.I. Anne Davis, Co-I. C Westhoff.

NICHD-R01-HD045786 Obesity, ovarian suppression and oral contraceptives. 7/1/05– 6/30/08. P.I.

CDC S2098-22/23- Start Now: Preventing Unintended Pregnancy among teens. P.I. V. Rickert, Co-I. C. Westhoff.

NICHD-R03-HD048547 Oral contraceptives and cytochrome p450 inducers. 12/1/04-11/30/06. P.I. A. Davis, Co-I. C. Westhoff.

NICHD-R01-HD047816 Oral Contraceptive use along the US-Mexico border. 7/1/05 – 6/30/10. P.I. J. Potter, Consultant, C. Westhoff

Duramed (Investigator Initiated) – Oral Contraceptive Pharmacokinetics in thin versus obese women. 4/2006-3/2008. P.I.

New York City Department of Health. Emergency Contraception Awareness & Access Program (ECAAP). 4/1/06-4/1/09. Co Investigator.

NICHD HD43374002 Contraceptive Clinical Trials network: Clinical Tiral of a novel hormonal contraceptive ring. 12/06 – 12/08 P.I.

DHHS/OPA PAR-05-185 Impact of pack supply on contraceptive continuation. 9/05 – 9/08. P.I. K. O'Connell, Co-I C Westhoff

Affinity Health Plan. "Txt now 2 decrease pregnancies L8tr" (a randomized trial of text messaging for OC continuation). 1/07 – 12/08, P.I. P. Castano, Co-I. C Westhoff

William and Flora Hewlett Foundation (2003-8871). Contraceptive Research and Training. 7/07 – 6/10 P.I. C. Westhoff

Organon/Rumba Oral Contraceptive Study. Study to determine safety and contraceptive efficacy and mentstrual cycle control of a vaginal ring. 5/06 – 4/08, P.I. C. Westhoff

Bayer/Yaz Study to assess folate levels in RBC during oral administration of OC containing folate. 1/07-12/07 P.I. P Castano, Co-I C. Westhoff

12) **Departmental and university committees**

Department of Obstetrics and Gynecology

1. Medical Records Committee 1986-89.
2. Family Planning Quality Assurance Committee 1989-**present** (chair).
3. Vanderbilt Clinic-4 Board of Managers 1989-95.
4. Departmental I.R.B. 1991 - 96
5. Departmental Executive Management Committee 2002-**present**.
6. Chair, Departmental Committee on Appointments & Promotions, 2008-

School of Public Health

1. Division of Epidemiology, Ph.D. Subcommittee 1990-1998
2. Standing Committee on Research 1990-**present**.
3. Center for Population and Family Health, Family Planning Clinics, Senior Staff committee, 1989 - **present**.
4. SPH Steering Committee, 1994-95.
5. Division of Health Policy, ad hoc search committee for chairman, 1995.
6. Center for Population and Family health, Research review committee, 1997- **present**.
7. Gonorrhea Community Action Project (GCAP). Advisory Committee, 1997-99.
8. Committee on Appointments and Promotions, 2006 - **present**

Curriculum Revision Committee, College of Physicians & Surgeons, working group on sexuality and reproductive health (chair) 1991-94.

Comprehensive Cancer Center. Ad hoc committee to reinstitute the CPMC tumor registry. 1992.

Comprehensive Cancer Center. Women's Cancers Program (chair). 1993 -96.

Comprehensive Cancer Center. Advisory Committee. 1993 - 96.

P & S Faculty Council. 1994 - 2007

Cancer Protocol Review Committee. 1994 - 95.

Institutional Review Board (including administrative committee). 1996 – 2000. Alternate, 2003-**present**.

CUMC, Committee to Review Complaints 2002-**present**.

13) **Teaching responsibilities**...

Department of Obstetrics and Gynecology

1. Biostatistics, 1987,1989,1991,1993. Enrollment: 6 clinical post-doctoral fellows per semester.
2. Journal Club for residents, monthly 1987 -1996.
3. Lectures to third year medical students, 16 hours per year since 1989.
4. Contraceptive options for the 1990's. June, 1991. Eight-hour CME course (course director).
5. Division of Prevention and Ambulatory Care, Division research meeting 1 hour weekly since 2001.

College of Physicians & Surgeons

1. Epidemiology section leader, first year medical students, 1987-90, 1992.
2. Sexuality and Reproduction (for Clinical Practice course), first - third year medical students. 1993 - **present**.
3. Reproductive Health (course director), fourth year elective, 1995 onward. (vanguard site for the AMWA Reproductive Health Initiative).
4. Clinical Practice I selective supervisor, for 1st Year medical students, 1996-2004.
5. Fourth year medical students, clinical selective, monthly, 1997-**present**
6. Pharmacology, second year students, Contraception, 1998-**present**.

Division of Epidemiology, School of Public Health

Epidemiology 6400, guest lecturer, 3 semesters per year – 1990-99.
-screening methodology
Epidemiology 9400, guest lecturer,1999.
-doctoral tutorial, endometrial or breast cancer
Epidemiology 8422, guest lecturer
Epidemiology 9480, course director, fall, 1990
Comprehensive examinations, 1991, 1993, 1995, 1996
General exams
Specialty exams (cancer).
Thesis sponsorships
E. Gollub, Dr.P.H., 2/91
J. Britton, Ph.D., 7/98
S. Kizelnik, Ph.D., 7/02
C. Morroni, Ph.D., 5/07

Thesis examination committees

J. Sackoff, Ph.D., 5/92
P. Murphy, Dr.P.H., 6/93
D. Maine, Dr.P.H., 6/98 (chair)
X. Shu, Ph.D., 6/93
J. Jacobson, Ph.D., 6/95 (chair)
L. Samelson, 4/97 (chair)
M. Latka, 7/97 (chair)

Master's degree student advisor

M.C. Randall, K. Murphy, M. Jacobs, A. Davis, L. De Nonno, S. Teal, N. New, C. Morroni (University of Capetown), Katharine O'Connell, P. Castano, J. Shafer, R. Sneed, Y. Swica, M. Minguez (Mt. Sinai School of Medicine), A.G. Thomas (Mt. Sinai School of Medicine), C. Robilotto, D. Horowitz, M Tepe, L. Rosenblatt, C. Galvao, A. Dempsey, M. Dragoman, Aileen Langston, Noa'a Shimoni.

14) **Other professional activities**

Editorial

1. Co-editor, Dialogues in Contraception, 1992-**present**.
2. Editorial board, CONTRACEPTION, 1993-**present**.
3. Editorial Board, AMA, Women's Health Web Site, 1997-1999.
4. Editorial Board, Managed Care Interface in Practice: Women's Health Issues, 1998.
5. Editorial Board, Expert Connections Forum (e-mail/web-based physician education program). 1998-99.
6. Editorial Board, The Forum (for women's health care), 2004-2007
7. Peer reviewer

American Journal of Epidemiology
American Journal of Obstetrics and Gynecology
American Journal of Public Health
Contraception
Epidemiology
Fertility and Sterility
Gynecologic Oncology
Journal of American Medical Women's Association
Journal of the American Medical Association
New England Journal of Medicine
Obstetrics and Gynecology
Perspectives in Sexual and Reproductive Health

Consultative (federal)

1. NHLBI. Member, ad hoc review group, Postmenopausal estrogen and progestin intervention (PEPI) trial. 1987.
2. Office of Technology Assessment (Preventive Services under Medicare Project). Cervical Cancer Screening in Elderly Women; scientific advisory group, 1988-89.
3. NICHD. Member, Contraception and Sexually Transmitted Disease Advisory Group, 1989.
4. NICHD. Member, Advisory Working Group on Breast Cancer and Oral Contraceptives, 1989 - 91.
5. NICHD. Member, ad hoc review groups, and site visitor, 1990 – **present.**
6. NIH, DRG. Epidemiology and Disease Control-2 study section, special reviewer, 1991 - 1993.
7. NCI. Ovarian cancer epidemiology advisory group, 1991.
8. NIH, DRG. Epidemiology and Disease Control-2 study section, member, 1994 - 1997.
9. NIH. Consensus Conference on Ovarian Cancer, speaker. 1994.
10. NCI. PLCO Trial, Monitoring and Advisory Panel, 1995 –**present.**
11. NICHD. Research on Long-acting Contraception, panel, 1995.
12. NIH. Consensus Development Conference on Breast Cancer Screening In Women aged 40-49. Panel member, 1996-97.
13. NICHD. Efficacy trial of spermicidal agents (FHI). Data Safety and monitoring Board, chair. 1998-2005.
14. Agency for Health Care Policy and Management. Ms trial. Data Safety and Monitoring Board, chair. 1998-2004.
15. Agency for Health Care Policy and Management (now ARHQ). U.S. Preventive Services Task Force, member, 1998-2003.
16. NICHD. Contraceptive Research and Evaluation Branch. Program Advisory committee, July, 1999.
17. NICHD. Fertility Regulation and Systemic Hormones in HIV-infected and at-risk Women, January 2003.
18. NICHD, DMPA and Diabetes Work Group, November 2003.
19. NICHD, Contraceptive Clinical Trials Network, Steering Committee, 2004 - **present.**

Consultative (non-federal)

1. Planned Parenthood of New York City. Member, medical committee 1991-94, Chair 1994 - 2006. Board of Directors,1994- 2006.
2. Planned Parenthood of New York City. Clinician Training Initiative.
3. Tobacco-Related Disease Research Program (State of California). Member, epidemiology study section, 1993 - 94.
4. American Medical Women's Association. Reproductive Health Initiative Advisory Committee, chairman, communications subgroup. 1993 -1995. Co-chair, 1995-1999, Chair 1999-2004.

5. ACOG, District II. Member, primary care committee. 1994 - 95.
6. Physicians for Reproductive Choice. Steering committee 1993 - 95.
7. NARAL Foundation, Advisory Committee, 1997- 2005.
8. Japanese Professional Women's Coalition for Sexuality and Health. International Advisor. 1997- 2000.
9. ACLU Reproductive Rights Project, affidavits and testimony for plaintiff in Michigan, New Jersey, and others. 1997-2003.
10. Open Society Institute, Reproductive Rights Program. Fellowship project evaluation. 1998-2000.
11. The Kenneth J. Ryan Residency Training Program in Abortion and Family Planning. Advisory Board member, 1999-**present**.
12. Royal College of Obstetricians and Gynecologists, Sexual and reproductive health in the medical curriculum, expert consultation, 2001
13. The Good Housekeeping Award for Women in Government, Selection Committee member, 2002 - 2005
14. The Medical Abortion Education Project (MAEP), Curriculum Development and Faculty Training. Jointly sponsored by NAF, PRCH, ARHP and AMWA, May 2001, March 2002, February 2003, April 2004.
15. ACOG District II, Emergency Contraceptive Advisory Board. 2002.
16. ACOG District II, Chlamydia Testing Workgroup. 2002.
17. Planned Parenthood Federation of America, National Medical Committee. Chair, Specialized Services Committee. Member, Executive Committee 2003-**present**. Vice-Chair 2006-2007, Chair 2008-2010.
18. Association of Reproductive Health Professionals, Board of Directors, 2003-**present**
19. Association of Professors of Gynecology and Obstetrics, Women's Health Interdisciplinary Curriculum Development Panel, 2003-
20. AMWA Foundation Board of Directors, 2004-2005.
21. Royal College of Obstetricians and Gynaecologists. Fertility control, 49th RCOG Study Group, 2005.
22. Alan Guttmacher Institute, Board of Directors, 2005-2008.
23. Fitness Magazine. Advisory Board-2007.
24. ACO6 District II. Legislative Committee. 2006-**present**.
25. Accreditation Committee on Graduate Medical Education (ACGME). Obstetrics and Gynecology Residency Review Committee. 2008 – **present**.
26. Planned Parenthood Federation of America, Board of Directors, 2008-2010.

15) **Publications**

Peer-reviewed

1. WESTHOFF C, Beral V: "Patterns of ovarian cyst hospital discharge rates in England and Wales, 1962-1979." British Medical Journal. 1984; 289:1348-9.

2. Howe G, WESTHOFF C, Vessey M, and Yeates D: "Effects of age, cigarette smoking and other factors on fertility; findings in a large prospective study." British Medical Journal. 1985; (290)1697-700.

3. Vessey M, Metcalfe A, Wells C, McPherson K, WESTHOFF C and Yeates D: "Ovarian Neoplasms, Functional Ovarian Cysts and Oral Contraceptives British Medical Journal, 1987; 294:1518.

4. WESTHOFF C, Pike M, Vessey M: "Benign Ovarian Teratomas: Population-based Case-control Study." British Journal of Cancer, 1988; 58:93-98.

5. WESTHOFF C, Gollub E, Patel J, Rivera H, Bast R: "CA-125 Levels in Menopausal Women." Obstetrics and Gynecology, 1990; 76:428.

6. Rosen MG, Dickinson JC, WESTHOFF C: "Vaginal birth after cesarean: a meta-analysis of morbidity and mortality." Obstetrics and Gynecology, 1991; 77:465-70.

7. Sassone AM, Timor-Tritsch IE, Artner A, WESTHOFF C, Warren WB: "Transvaginal sonographic characterization of ovarian pathology: Evaluation of a new scoring system to predict ovarian malignancy." Obstetrics and Gynecology, 78:70-76, 1991.

8. WESTHOFF C, Randall MC: "Ovarian cancer screening - potential effect on mortality." American Journal of Obstetrics and Gynecology, 1991; 165:502-5.

9. Kelly A, Marks F, WESTHOFF C, Rosen M. The effect of the New York State restrictions on resident work hours. Obstetrics and Gynecology, 1991; 78: 468-73.

10. WESTHOFF C, Clark C: "Benign ovarian cysts in the United States and England & Wales." British Journal of Obstetrics and Gynecology 1992; 99:329-32.

11. WESTHOFF C, Levin B, Ladd G, O'Connor J: "Sources of variability

in normal CA-125 levels." Cancer Epidemiology, Biomarkers and Prevention, 1992; 1:357-9.

12. WESTHOFF C, Murphy P, Heller D, Halim A: "Is ovarian cancer associated with an increased frequency of germinal inclusion cysts?" American Journal of Epidemiology. 1993; 138:90-93.

13. WESTHOFF C, Marks F, Rosenfield A: "Residency Training in Contraception, Sterilization, and Abortion." Obstetrics and Gynecology 1993; 81:311-314.

14. Gollub E, WESTHOFF C, Timor-Tritsch I: "Detection of ovaries by Transvaginal Sonography in Postmenopausal Women." Ultrasound in Obstetrics and Gynecology. 1993; 3:422-425.

15. Gerber S, WESTHOFF C, Lopez M, Gordon L: "Norplant use in a New York City clinic population". Contraception. 1994; 49:557-564.

16. WESTHOFF C: Current status of ovarian cancer screening. Gynecologic Oncology, 1994; 55:S34-S37.

17. WESTHOFF C: Abortion training in residency programs. JAMWA 1994 49:150-2.

18. Bass K, WESTHOFF C, Bush T: "Ovarian cancer: Epidemiologic and clinical perspectives and the feasibility of screening. Menopause. 1995; (2):145-158.

19. WESTHOFF C, Wieland D, Tiezzi L: Depression in users of Depot medroxyprogesterone acetate. CONTRACEPTION 51:351-354, 1995.

20. WESTHOFF C, Gentile G, Lee J, Zacur H, Helbig D. Predictors of ovarian steroid secretion in reproductive age women. American Journal of Epidemiology 1996; 144:381-89.

21. Heller D, Gordon R, WESTHOFF C, Gerber S. Asbestos exposure and ovarian asbestos fiber burden. American Journal of Industrial Medicine 1996; 29:435-39.

22. Heller D, WESTHOFF C, Gordon R. The relationship between perineal cosmetic talc usage and ovarian talc particle burden. American Journal of Obstetrics and Gynecology 1996; 174:1507-10.

23. WESTHOFF C. Current assessment of the use of intrauterine

devices. J. Nurse-Midwifery. 1996; 41:218-23.

24. WESTHOFF C. Ovarian Cancer. Ann Rev Pub Hlth. 1996; 17:85-96.

25. WESTHOFF C. Oral contraceptives and venous thromboembolism: Should epidemiologic associations drive clinical decision making? Contraception. 1996; 54:1-3.

26. Zacur H, Kaufman S, Smith B, WESTHOFF C, Helbig D, Lee Y, Gentile G. Does creatinine adjustment of urinary pregnanediol glucuronide reduce or introduce measurement error? Gynecol. Endocrinol.. 1997; 11:29-33.

27. Pirog E, Heller D, WESTHOFF C. Endometrial Adenocarcinoma - Lack of Correlation between Treatment Delay and Tumor Stage. Gynecol. Oncol., 1997, 67:303-308.

28. National Institutes of Health Consensus Development Panel. NIH Consensus Statement: Breast Cancer Screening for Women 40-49. Journal of the National Cancer Institute 1997; 89:1015-26.

29. Neu N, Grumet S, Saiman L, McMahon D, WESTHOFF C. Genital chlamydial disease in women: novel risk factors in a low prevalence population. Sex Trans Dis 1998; 25:317-21.

30. WESTHOFF C, Truman C, Kalmuss D et al. Depressive symptom and Norplant Contraceptive Implants. Contraception, 1998; 57:241-45.

31. WESTHOFF C, Truman C, Kalmuss D et al. Depressive symptoms and Depo-provera, Contraception, 1998; 57:237-240.

32. WESTHOFF C. Oral contraceptives and thrombosis: an overview of study methods and recent results. Am J Obstet Gynecol 1998; 179: S38-S42.

33. Winikoff B, Ellertson C, Elul B, Sivin I for the Mifepristone Clinical Trials Group. Acceptability and feasibility of early pregnancy termination by mifepristone-misoprostol: results of a large multicenter trial in the U.S. Arch Fam Med 1998; 7:360-66.

34. WESTHOFF C for the IFFS Evaluating Committee. Consensus Statement on combination oral contraceptives and cardiovascular disease.

35. IFFS newsletter, autumn, 1998 (also published on the web at

http://www.mnet.fr/iffs), Fertility & Sterility 6/99(supplement).

36. WESTHOFF C. Breast cancer risk: perception versus reality. Contraception. 1999; 59(1S):25S-28S.

37. Davis A, WESTHOFF C, De Nonno L. Bleeding patterns after early abortion with mifepristone and misoprostol or manual vacuum aspiration. J Am Wom Med Assn. 2000; 55:141-144.

38. WESTHOFF C, Heller D, Drosinos S, Tancer ML. Risk factors for hyperplasia-associated versus atrophy-associated endometrial carcinoma. Am J Obstet Gynecol. 2000; 182:506-508.

39. Britton J, WESTHOFF C, Howe G, Gammon M. Diet and benign ovarian tumors (United States). Cancer Causes and Control. 2000; 11:389-401.

40. WESTHOFF C. Evidence-based medicine: an overview. Int J. Fert. 2000; 45(suppl):57-63.

41. Batya E, Pearlman E, Sorhaindo A, Simonds W, WESTHOFF C. In depth interviews with medical abortion clients: Thoughts on the method and home administration of misoprostol. JAMWA, 2000; 55:169-172.

42. WESTHOFF C, Britton J, Gammon M, Wright T, Kelsey J. Oral contraceptives and benign ovarian tumors,. Am. J Epidemiol. 2000; 152; 242-246.

43. WESTHOFF C, Davis A. Tubal sterilization: focus on the United States esperience. Fertil & Steril 2000; 73:913-22.

44. WESTHOFF C, Dasmahapatra R, Winikoff B, Clarke S. Predictors of analgesic use during supervised medical abortion. Contraception. 2000; 61:225-229.

45. WESTHOFF C, Murphy P, Heller D. Predictors of ovarian follicle number. Fertil. and Steril. 2000; 74(4):624-628.

46. Schaff E, Fielding S, WESTHOFF C. Ellertson C, Eisinger S, Stadalius L, Fuller L,. Vaginal misoprostol administered 1, 2, or 3 after mifepristone for abortion. A randomized trial. JAMA. 2000; 284(15):1948-53.

47. Britton J, WESTHOFF C, Gammon M, Wright T. Lactose and benign

ovarian tumors in a case-control study. Br J Cancer. 2000; 83 (11): 1552-55.

48. WESTHOFF C. Oral contraceptives and cardiovascular risk: an end to the debate? Contraception, 2000; 62:1S-2S.

49. De Nonno L.J., WESTHOFF C, Fielding S, Schaff E, Timing of pain and bleeding after mifepristone-induced abortion. Contraception. 2000; 62:305-9.

50. WESTHOFF C, Dasmahaptra R, Schaff E. Analgesic during at-home use of misoprostol as part of a medical abortion regimen. Contraception, 2000; 62:311-14.

51. Elul B, Pearlman E, Sorhaindo A, Simonds W, WESTHOFF C. In-depth interviews with medical abortion clients: thoughts on the method an home administration of misoprostol. J Am Med Womens Assoc. 2000; 55(3S):169-72.

52. Allen R, WESTHOFF C, DeNonno L, Fielding S, and Schaff E. Curettage after mifepristone induced abortion. Frequency, timing and indications. Obstet Gynecol. 2001; 98:101-6.

53. Guise J-M, Mahon SM, Aickin M, Helfand M, Peipert JF, and WESTHOFF C. Screening for bacterial vaginosis in pregnancy. Am J Prev Med. 2001; 20:62-72.

54. Davis AR and WESTHOFF C. Primary dysmenorrhea in adolescent girls and treatment with oral contraceptives. J. Ped Adol Gyn 2001; 14:3-8.

55. Schaff EA, Fielding SL, WESTHOFF C. Randomized trial of oral versus vaginal misoprostol at one day after mifepristone for early medical abortion. Contraception 2001; 64(2):81-5.

56. WESTHOFF C. Criteria for appropriate birth control. Gynecol Endocrinol. 2001; 15(Suppl 3):19-22.

57. Davis AR, Nowygrod S, Shabsigh R and WESTHOFF C. The influence of vaginal bleeding on the sexual behavior of urban, Hispanic women and men. Contraception 2002; 65:351-355.

58. WESTHOFF C, Kerns J, Morroni C, Cushman L, Tiezzi L and Murphy PA. Quick start: a novel oral contraceptive initiation method. Contraception 2002; 66:141-145.

59. Berg AO, Allen JD, Frame PS, Homer CJ, Lieu TA, Mulrow CD, Orleans CT, Peipert JF, Pender NJ, Sox HC Jr, Teusch SM, WESTHOFF C, Woolf SH. Screening for chlamydia infection: recommendation and rationale. Am J Nurs. 2002; 102(10:87-92.

60. Schaff EA, Fielding SL, WESTHOFF C. Randomized trial of oral versus vaginal misoprostol 2 days after mifepristone 200 mg for abortion up to 63 days of pregnancy. Contraception 2002; 66(4):247-50.

61. Berg AO, Allen JD, Frame PS, Homer CJ, Johnson MS, Klein JD, Lieu TA, Mulrow CD, Orleans CT, Peipert JF, Pender NJ, Siu AL, Teutsch SM. WESTHOFF C, Woolf SH. Newborn hearing screening: recommendations and rationale. Am J Nurs. 2002; 102(11):83-9.

62. WESTHOFF C, Morroni C, Kerns J, and Murphy PA. Bleeding patterns after immediate versus conventional oral contraceptive initiation: a randomized controlled trial. Fertility and Sterility 2003; 79:322-329.

63. WESTHOFF C. Picardo L, and Morrow E. Quality of life following early abortion: A comparison of medical and surgical approaches. Contraception. 2003; 67:41-47.

64. WESTHOFF C. Depot-medroxyprogesterone acetate injection (Depo-Provera): a highly effective contraceptive option with proven long-term safety. Contraception, 2003; 68:75-87.

65. Guise JM, Palda V, WESTHOFF C, and Lieu TA. The effectiveness of primary care-based interventions to promote breastfeeding. Systematic evidence review and meta-analysis. Annuals of Family Medicine 2003; 1:70-78.

66. WESTHOFF C, and the U.S. Preventive Services Task Force. Behavioral Intervention to promote breastfeeding: Recommendations and rationale. Annals of Family Medicine. 2003; 1:79-80

67. WESTHOFF C. Emergency Contraception. NEJM 2003; 349:1830-35.

68. Kerns J, WESTHOFF C, Morroni C, Murphy PA. Partner influence on early oral contraceptive discontinuation in a predominantly Hispanic population. Perspectives on Sexual and Reproductive Health. 2003.

69. Gilles JM, Creinin MD, Barnhart K, WESTHOFF C, Frederick MM, Zhang J. A randomized trial of saline solution-moistened misoprostol versus dry misoprostol for first trimester pregnancy failure. Am J Obstet Gynecol. 2004; 190:389-94.

70. Creinin MD, Harwood B, Guido R, Fox MC, WESTHOFF C and Zhang J for the NICHD Management of Early Pregnancy Failure Trial. Endometrial thickness after misoprostol use for early pregnancy failure. Intl. J. Gyncol & Obst. 2004; 86:22-26.

71. Brinton LA, Lamb EJ, Moghissi KA, Scoccia B, Althuis MD, Mabie JE and WESTHOFF CL. Ovarian cancer risk following use of ovulation-stimulating drugs. Obstet Gynecol. 2004; 103(6):1194-203.

72. Brinton LA, Scoccia B, Moghissi KA, WESTHOFF CL, Althuis MD, Mabie JE, Lamb EJ. Breast cancer risk associated with ovulation-stimulating drugs. Hum Reprod. 2004:19(9):2005-13.

73. Brinton LA, Lamb EJ, Moghissi KA, Scoccia B, Althuis MD, Mabie JE and WESTHOFF CL. Cancer risk after the use of ovulation-stimulating drugs. Obstet Gynecol Surv. 2004; 59(9):657-659.

74. Creinin MD, Fox M, Teal S, Chen A, Schaff E, Meyn L, WESTHOFF C. A randomized comparison of Misoprostol 6 to 8 hours versus 24 hours after Mifepristone for Abortion. Obstet Gynecol. 2004; 103(5):851-859.

75. Morroni C, Grams Morgan, Tiezzi L and WESTHOFF C. Immediate monthly combination contraception to facilitate initiation of the Depo-medroxy progesterone acetate contraceptive injection (DMPA). Contraception 2004; 70:19-23.

76. Davis AR, Robilotto C, WESTHOFF C, Forman S, and Zhang J for the NICHD Management of Early Pregnancy Failure Trial Group. Bleeding patterns after vaginal misoprostol for treatment of early pregnancy failure. Hum Reprod. 2004:19(7):1655-8.

77. Brinton LA, Lamb EJ, Moghissi KS, Scoccia B, Althuis MD, Mabie JE, WESTHOFF CL. Ovarian cancer risk associated with varying causes of infertility. Fertil. & Steril. 2004; 82(2):405-14.

78. Brinton L, Scoccia B, Moghissi K, WESTHOFF C, Althuis M, Mabie J, Lamb E. Breast Cancer risk associated with ovulation-stimulating drugs. Human Reproduction, 2004; 19(9):2005-13.

79. Althuis M, Moghissi K, WESTHOFF C, Scoccia B, Lamb E, Lubin J, Brinton L. Endometrial cancer after use of clomiphene citrate for ovulation-induction. Am J Epid. 2005;161:607-615.

80. Sneed R, WESTHOFF C, Morroni C, Tiezzi L. A prospective study of immediate initiation of depo medroxyprogesterone acetate contraceptive injection. Contraception 2005;71:99-103..

81. Murphy P, Kern S, Stanczyk F, WESTHOFF C. Interaction of St. John's Wort with oral contraceptives: Effects on the pharmacokinetics of norethindrone and ethinyl estradiol, ovarian activity, and breakthrough bleeding. Contraception 2005;71(6):402-8.

82. Heller D, Murphy P, WESTHOFF C. Are germinal inclusion cysts markers of ovulation? Gynecologic Oncology 2005; 96:496-99..

83. Nansel TR, Frederick MM, Doyle F, Zhang J for the NICHD Management of Early Pregnancy Failure Trial Group. Quality of life in women undergoing medical treatment for early pregnancy failure. In press,

84. Brinton LA, Moghissi K, Scoccia B WESTHOFF C, Lamb EJ. Ovulation induction and cancer risk. Fertility & Sterility 2005;83:261-274.

85. Sonnenberg F, Burkman R, Speroff L, WESTHOFF C, Hagerty C. Cost-effectiveness and contraceptive effectiveness of the transdermal contraceptive patch. Am J Obstet Gynecol 2005;192:1-9.

86. Brinton L, WESTHOFF C, Scoccia B, et al. Causes of Infertility as predictors of subsequent cancer risk. Epidemiology 2005;16:500-507.

87. WESTHOFF C. Contraceptive choices for HIV-infected and at-risk women: review of available contraceptives. JAIDS 2005;38:S3.

88. Althuis MD, Moghissi KS, WESTHOFF CL, Scoccia B, Lamb EJ, Lubin JH, Brinton LA. Uterine cancer after use of clomiphene citrate to induce ovulation. Am J Epidemiol. 2005 Apr 1;161(7):607-15.

89. Zhang J, Gilles J, Barnhart K, Crenin M, WESTHOFF C, Frederick M, for the National Institute of Child Health and Human Development Management of Early Pregnancy Failure Trial. Medical Management with misoprostol for early pregnancy failure: A multi-center randomized trial.

New Eng J Med 2005;353: August 18.

90. Althuis MD, Scoccia B, Lamb EJ, Moghissi KS, WESTHOFF CL, Mabie JE, Brinton LA. Melanoma, Thyroid, cervical, and colon cancer risk after use of fertility drugs. Am J Obstet Gynecol. 2005 Sep;193:668-74.

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C. **Reviews, chapters, letters, editorials**

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D. **Published Abstracts**

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49. Castaño PM, WESTHOFF CL. A new tool for assessing the folate status of reproductive-aged urban Latina women. Poster presented at the ACOG 55th Annual Clinical Meeting, May 8, 2006.

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55. Gorin, S, Franco, R, Hajiani, F, WESTHOFF, C, New York Physicians Against Cancer Study Group, Columbia University, New York, NY. Physician Intentions and HPV Vaccination: The First Year. 2007: AACR International Conference on Frontiers in Cancer

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56. O'Connell, K, WESTHOFF, C Pharmacology of Hormonal Contraceptives and Acne. CUTIS, Jan 2008; 81 (suppl 1):8-12

57. Gorin S, Franco R, WESTHOFF C, New York Physicians Against Cancer Group. HPV vaccinations one year post FDA approval. 2008 ASCO (submitted).

58. Gorin S, Franco R, Hajiani F, WESTHOFF C, New York Physicians against Cancer Study Group. Columbia University, New York, NY.

59. Guiahi M, WESTHOFF C. Integrating a Family Planning Curriculum into a Faith Based Obstetrics & Gynecology Residency program: A Six-Step approach (submitted).

16) **Presentations at professional meetings: (1995-2005)**

Grand Rounds Speaker, Departments of Obstetrics and Gynecology (1995-**present)**

Wayne State University, Detroit, Mi 5/05
Northwestern University, Chicago, Ill. 5/05
Newark-Beth Israel Medical Center, Newark NJ, 4/05
SUNY Stony Brook, 3/05
UC-San Diego, 2/05
University of Miami, 12/04
Tufts University, Boston, 11/04
University of Mass, Baystate Medical Center, 6/04
University of South Carolina, Columbia SC, 6/04
Long Island College Hospital, Innovations in Family Planning, Brooklyn, NY 5/04.
University of California, San Francisco. Innovations in initiation of hormonal contraception. 1/04
SUNY Downstate, Vaginal Hormonal Contraception, Brooklyn, NY 1/04.
Morristown Hospital, Medical Abortion Regimens, New Jersey. 11/02.
Overlook Hospital, Medical Abortion Regimen, New Jersey. 11/02.
Maimonides Medical Center, Epidemiology and Women's Health, Brooklyn, NY. 5/02.
Thomas Jefferson University, Early Abortion, Philadelphia, PA 02/02.
Washington University, Saint Louis, MO, Medical Abortion, 03/02.
Metropolitan Hospital Center, Intrauterine Contraception, NY, 10/01
Long Island Jewish Medical Center, Mifepristone. New York, 1/01.
University of Medicine and Dentistry of Newark, New Jersey, Evidence-

based medicine in OB/GYN. New Jersey , 9/00.
Saint Vincent's Hospital, Emergency Contraception: What It Is and What It Is Not. New York, 12/99.
New York Methodist Hospital, New Alternatives in Termination of Pregnancy. New York 11/99.
Jamaica Hospital Center, Evidence-based medicine and contraception. Queens, NY, 10/99.
Beth Israel Medical Center, Intrauterine contraception in the US: a current perspective. New York, 9/99.
Bronx-Lebanon Hospital Center, Oral Contraceptives: Evidence-Based Clinical Decisions, New York, 7/99.
St. Luke's/Roosevelt Hospital Center. Emergency Contraception. New York 3/99.
Lincoln Medical and Mental Health Center. Intrauterine Contraception in the U.S.A. A Current Perspective. Bronx, NY10/98.
CPMC Scholarly Debates: Mammography from ages 40-49. 2/98
University of Rochester, Epidemiology of Benign Ovarian Tumors. New York 11/97.
Long Island Jewish Medical Center. Risks and benefits of oral contraceptives, New York 10/97.
St. Luke's/Roosevelt Hospital Center. Epidemiology of Benign Ovarian tumors. NY 9/97.
Methodist Hospital, Benefits and risks of oral contraceptives. Brooklyn, NY 5/97.
University of Illinois at Chicago, Intrauterine Contraception in the U.S.: A Current Perspective, Chicago, IL 3/97.
Albert Einstein College of Medicine, The IUD in Evolution. 5/96.
United Health Services Hospitals, Ovarian Cancer. Binghamton, New York 12/95.
Hackensack Hospital, Cardiovascular risks associated with oral contraceptive use, Hackensack, N.J. 5/95.
Georgetown University, Oral contraceptive use in perimenopausal women. 3/95.
Maine Medical Center, IUD's. 2/95.
Roosevelt Hospital Center (NYC), Non-contraceptive risks and benefits of OC's. 2/95.

Other venues:

David Feld Memorial Lecture, Wayne State University, 6/05.

ACOG Annual Clinical Meeting, Postgraduate Course chair. Innovations

in Family Planning. San Francisco, Ca. 5/05.

9th Annual Pediatric, Adolescent and Young Adult Gynecology Conference, Mt. Sinai School of Medicine. Innovations in Contraceptive Initiation. 3/05.

Royal College of Obstetrics and Gynecology. Contraceptive Continuation, London, 2/05.

Miami Ob/Gyn Society, President's Guest Speaker. Innovations in Contraception, 12/04

Distinguished Lecture Series in Reproductive Endocrinology, Columbia University. Cancer after Infertility Treatment. 11/04

New York State Department of Health. The Family Planning Benefit Program: a Medicaid Waiver, panelist, Albany NY. 11/04

ASRM, 60th annual meeting. Cancer after Infertility Treatment, Symposium chair and speaker. Philadelphia, Pa. 10/04

Radcliffe Institute of Advanced Study, Harvard University, Reproductive Health in the 21st Century, New Technologies and the Unsettling of the Natural, Speaker. Cambridge, MA 10/04.

NAF, Risk Management Seminar, Program Chair, New York, NY 10/04.

Kings County Hospital Center. Early Options Center Dedication. Speaker, 9/04.

Bronx Gynecological and Obstetrical Society, Contraception, Bronx, NY 6/04.

ACOG Annual Clinical Meeting, Postgraduate Course chair. Innovations in Family Planning. Philadelphia, PA. 5/04.

Harvard Medical School, Lader Lecture. RU486, Plan B, and the Pharmacological Revolution in Reproductive Rights, Boston, MA, 5/04.

NAF Annual Meeting, Integrating Mifepristone into a Hospital Based Abortion Service: Problems encountered and solved, seminar. New Orleans, LI, 4/04.

San Francisco GYN Society, Innovations in Hormonal Contraception, San

Francisco, CA, 1/04.

AAMC Annual Meeting, Reproductive Health Initiative Workshop, Washington, DC, 11/03.

ACOG District II, Annual Meeting. Medical Abortion: Evaluation, management and administration. New York, NY 10/03

AAMC Annual Meeting, Reproductive Health Initiative Workshop, San Francisco, CA. 11/02.

ACOG District II, Annual Meeting. Medical Abortion in the US - a Historical Review. New York, NY.10/02.

ACOG District II, Annual Meeting. Chlamydia Screening and Infertility Prevention.

2nd C.O.G.I., IUD's & New Progesterone in OC's. Washington, DC. 6/02.

Women's and Infant's Hospital, Brown University, Visiting Professor, Providence, RI. 6/02.

Kaiser Family Foundation's briefing. What you need to know about the pill: The latest research and birth control's other coming attractions. New York, NY 6/02.

University of Michigan, Abram Sager MD Lectureship, Resident Paper Day. Ann Arbor, Michigan. 5/02.

ACOG Annual Clinical Meeting Postgraduate course director (060) on Contraception and Abortion, Los Angeles, CA. 5/02.

Department of Health and Human Services, 2002 National STD Prevention Conference, Chlamydia Screening and Infertility Prevention (plenary lecture), San Diego, CA 3/02.

ARHP Clinical Update on Transcervical Sterilization, History and epidemiology of sterilization in the U.S. Baltimore, MD 12/01.

New York City Department of Health Preventive Medicine Residency Program, Controversies in Screening: Mammography. New York 12/01.

IFFS Nuvaring Symposium chairperson, Melbourne, Australia 11/01.

American Society for Reproductive Medicine, Roundtable, Management of Difficult Cases in Family Planning. Orlando, FL 10/01.

ASRM Women's Council Breakfast, Contributions of Epidemiology to Women's Health. Orlando, FL 10/01.

ACOG District II, Annual Meeting, Medical Abortion. New York, 10/01.

ACOG Annual Clinical Meeting, Irving Cushner Lecture. Contraception: The Next 50 Years. Chicago, IL 5/01.

College of Pharmacy Washington State University, Allen I. White Lecture. Medical Abortion Clinical Aspects. Spokane, WA. 4/01.

ACOG Annual Clinical Meeting, Postgraduate course (060) on Contraception and Abortion, Chicago, IL. 4/01.

Medical College of Georgia, Serono Symposium: Frontiers in Reproductive Endocrinology. Innovations in Contraception. Washington, DC, 4/01.

New York City Council RU486 Public Hearing: The Impact of Possible FDA Restrictions on its Use and Distribution. 9/00.

FIGO, Annual Meeting, New Developments in Injectable Contraception, A CME Symposium, Washington, DC 9/00.

The Congress of the European Society of Contraception. Long Term Contraception. Ljubljana, Slovenia, 6/00.

University of Kansas Medical Center. Evidence Based Medicine...What Does It Really Mean? Visiting Professor. Kansas City, Kansas. 6/00.

ACOG Annual Clinical Meeting, Postgraduate Course (060) on Contraception and Abortion, San Francisco, CA, 5/00.

Population Council Oral contraceptives and benign ovarian tumors. 12/99.

Planned Parenthood, Advances in Reproductive and Sexual Health, New York, 11/99.

World foundation for studies in women's health. 4th annual meeting. Evidence-based medicine. San Francisco, 10/99.

Planned Parenthood of New York City. Advances in Reproductive and Sexual Health. 10/99.

Naral/NY Foundation. Barriers in Residency Training and Solutions. New York 8/99.

Bronx Gynecological Society, Evidence-based medicine in obstetrics and gynecology.. 7/99.

Population Council, Mifepristone Meeting. 6/99.

Evidence-based medicine and oral contraceptives. Symposium Chair, New York 6/99.

University of Minnesota/Health Learning Systems, Making Evidence-based Clinical Decisions. Philadelphia, PA. 5/99.

University of Minnesota CME program. Evidence-based medicine and oral contraceptives. Chicago, 3/99.

University of Minnesota CME program. Evidence-based medicine and oral contraceptives. San Diego, CA 1/99.

International Symposium on Women's Health in a Changing Society. Informed choice of contraception -- evidence-based. Tokyo 12/98.

Congress of the European Society of Contraception, Oral contraceptives and cardiovascular disease: an end to the debate (symposium chairperson). Prague 6/98.

North American Society for Pediatric and Adolescent Gynecology, 12th Clinical meeting. Smoking and reproductive health (Keynote address). Palm Beach, Florida 5/98.

North American Society for Pediatric and Adolescent Gynecology,12th Clinical meeting. Changing philosophy of contraception. Palm Beach, Florida 5/98.

New York Gynecological Society. Residency training in family planning -- an update. NY, NY 3/98.

First International Symposium on Women's Health in a Changing Society. Hormonal contraception: safety and effectiveness. Tokyo, 11/97.

First International Symposium on Women's Health in a Changing Society. Hormonal contraception: safety and effectiveness. Osaka, 11/97

New York Obstetrical Society, Is there a future for Norplant? (discussant). NY, NY 11/97.

Emory University School of Medicine (CME program), Breast cancer controversies: screening and estrogen replacement therapy. 10/97.

New York Academy of Medicine. Emergency Contraception. 9/97.

FIGO Biannual meeting. Preventing teen pregnancy. Copenhagen 8/97.

New York Academy of Medicine. Impact and implementation of medical abortion. 5/97.

National Campaign to Prevent Teen Pregnancy, Congressional Briefing on Teen Pregnancy Prevention Programs,. Washington, DC. 4/97.

National Workshop Series, Third Generation OCs. Palm Beach, FL. 11/96.

ARHP Conference, Women's Health in the Perimenopause, Ovarian Cancer. Amelia Island, FL. 11/96.

American Medical Women's Association Workshop. Women Empowering Women: World Population and Leadership, Boston MA 11/96.

American Medical Women's Association, 81st Annual Meeting, Reproductive health Initiative Workshop. 10/96.

National Nurse Practitioner Conference. Intrauterine contraception in the US: A current perspective. 10/96.

State University of New York, Alumni Day. Family planning and public health issues. 9/96.

University of Southern California. (CME meeting at ACOG annual meeting). Current controversy of cardiovascular safety associated with

oral contraceptives. 4/96.

Pennington Biomedical Research Center. Women's Health: Prevention is the Best Medicine Symposium. Ovarian Cancer. 3/96.

University of Texas Medical Branch at Galveston. Cardiovascular Risks in Women: New Strategies in Hormonal Therapies. Texas, 3/96.

University of Colorado CME teleconferences. Oral contraceptives: smoking and other cardiovascular risks. Multiple dates, 1996.

Sarah Lawrence College, Contraceptive Risks and Benefits: Controversial Issues, New York. 1/96.

Morristown Medical Center, Gyn. Oncology Update. 10/95.

Eastern Virginia Medical School, The physician's Role in Adolescent Health Care. 3/95.

Health Learning Systems, The fourth decade of oral contraception. Program development and faculty, 1993 - 1994. Multiple presentations, University of Minnesota CME program.

NIH, Consensus conference on ovarian cancer. Assessing ovarian cancer screening. Washington, DC .4/94.

American College of Nurse Midwives Annual Meeting. Intrauterine Contraception. Memphis, TN. 4/94.

AMWA, 78th Annual Meeting, Enhancing Communication About Sex. New York 11/93.

Population Council, Fourth International Symposium on IUD's. 3/92.

Cincinnati Ob/Gyn Society. 2/92.

New York University, Institute of Environmental Medicine. 12/91.

Family Planning Council of Western Pennsylvania, Eighth Annual Medical Update on Reproductive Health and Nutrition. 5/91.

Columbia University Continuing Education Courses

Third Annual Freda Symposium. Management of Miscarriage, and Update on second Trimester Abortion. 3/05

Cicatelli Associates Inc., Clinical issues in reproductive health, Update conference. Course Director. CU (CME) 5/03.

Update on implantable contraception method. Course Director. 9/98 at CPMC (CME mini-symposium).

Family Planning Issues: Cultural considerations for our Hispanic Patients,faculty. 6/97.

Advances and controversies in Ob/Gyn; medical abortion, faculty. 6/97.

Abortion Education Seminar: What You Won't Learn in Med School, 2/97.

Workshop "Train the Trainer", Faculty. 4/96.

The Evolution of Abortion Services, Seminar, 2/96.

Genetics in obstetrics and gynecology: Science and ethics, faculty. 6/95.

Fourth International Conference on Transvaginal sonography, faculty. 9/91.

Contraceptive options for the 1990's, course director. 6/91.

Endocrinology and Infertility Update: Current trends and New Horizons, faculty. 3/89.

28th Annual Postgraduate Course in Obstetrics and Gynecology, faculty. 10/88.